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EXAMINER

1615

ART UNIT

PAPER NUMBER

02/01/01

5

DATE MAILED:

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No. 09/437,419	Applicant(s) Vijay Kumar
Examiner P. Kulkoosky	Group Art Unit 1615

—The MAILING DATE of this communication appears on the cover sheet beneath the correspondence address—

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE ONE MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, such period shall, by default, expire SIX (6) MONTHS from the mailing date of this communication .
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).

Status

- Responsive to communication(s) filed on _____.
- This action is FINAL.
- Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

- Claim(s) 1 - 29 is/are pending in the application.
- Of the above claim(s) _____ is/are withdrawn from consideration.
- Claim(s) _____ is/are allowed.
- Claim(s) _____ is/are rejected.
- Claim(s) _____ is/are objected to.
- Claim(s) 1 - 29 are subject to restriction or election requirement.

Application Papers

- See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.
- The proposed drawing correction, filed on _____ is approved disapproved.
- The drawing(s) filed on _____ is/are objected to by the Examiner.
- The specification is objected to by the Examiner.
- The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119 (a)-(d)

- Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
 - All Some* None of the CERTIFIED copies of the priority documents have been received.
 - received in Application No. (Series Code/Serial Number) _____.
 - received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____.

Attachment(s)

- Information Disclosure Statement(s), PTO-1449, Paper No(s). _____ Interview Summary, PTO-413
- Notice of Reference(s) Cited, PTO-892 Notice of Informal Patent Application, PTO-152
- Notice of Draftsperson's Patent Drawing Review, PTO-948 Other _____

Office Action Summary

Art Unit: 1615

Claims 1-29 are generic to a plurality of disclosed patentably distinct species comprising polymer complexes in which polyvinyl pyrrolidone is combined with a carboxylic group-containing polymer. Provisional election is mandatory of one type of polymer which possesses a distinctive chemical structure. For example, claim 3 acrylics or all gums of this claim constitute separately species. Applicant is required under 35 U.S.C. 121 to elect a single disclosed species, even though this requirement is traversed.

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

During a telephone conversation with Ms. Wendy Marsh on January 24, 2001 a provisional election was made with traverse to prosecute the invention of an elected species consisting of acrylic and polyvinylacetate copolymers, claims 1-29 read upon the elected species. Affirmation of this election must be made by applicant in replying to this Office action. Claims 1-29 withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

Claims 3, 18 must be limited to the elected polymers.

Art Unit: 1615

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 1-29 are rejected under 35 U.S.C. 103(a) as being unpatentable over Gupta et al Drug Development and industrial pharmacy (1994) or M.A. Elegakey et al P.P.S. 434-440 or Takayana Chem. Pharm. Bull. PPS.4921 - 4926.

The combination of polyvinylpyrrolidone and carboxylic polymer is known in the art for properties of the complexes formed by same.

The examples in the specification wherein PVAP - PVP, drug complexes are formed are considered to be unobvious from the cited Prior Art disclosures. The claims do not clearly define a "complex" of PVAP/PVP, however, and may be physically equivalent to a mixture of ingredients in which PVAP is not complexed, but is added as an auxiliary component, i.e., as a plasticizer. A PVP mixture with PVAP as an additive would be obvious in view of the known plasticizing properties of PVAP. The PVAP - PVP complexes of the working examples are considered to be unobvious form the cited Prior Art information. The references clearly provide motivation for use of a variety of drugs encompassed in a PVP acrylic polymer matrix. Ibuprofen

Art Unit: 1615

would be obvious to those skilled in the art to use as an active in the preparations of the cited Prior Art.

Claims 1-29 are rejected under 35 U.S.C. 112, paragraph 2.

A complex such as is formed by the process of the working examples is not required in the claims. The physical structure of the "complex" as is reported by spectroscopic data is not included as a limitation, but is critical to the applicants' disclosed view of the invention (see pages 26-30).

The term "complex" is non-descriptive of the drug containing PVP/PVAP product which which is disclosed as possessing required release and physical properties.

Claims 1-28 are rejected under 35 U.S.C. 112, par. 1.

The claims are not supported for the scope of drug which can be encapsulated in the complex.

Ibuprofen and other actives of similar solubility and properties are presumed to be useful, but the specification does not explain the forces between drug and complex such as bonding, etc. which would enable the use of an unlimited number of species unrelated in chemical structure to ibuprofen. The drug, PVP and acrylic or phthalate copolymer are suggested to be limited to definite amounts of same in a structure of definite form. For example, a form as would be represented in a drawing.

References (A), (U) and (V) are cited of interest.

Kulkosky/LR



PETER F. KULKOSKY
PRIMARY EXAMINER